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EXAMINER	
ARCHIE, NINA	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,935	TSUKAHARA ET AL.	
	Examiner	Art Unit	
	Nina A. Archie	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/30/2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/8/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office is responsive to Applicant's amendment and response filed on 6-30-2009. Claims 1-6 and 9-10 are pending and under examination. Claims 7-8 are cancelled.

Sequence Requirements

2. This application contains a sequence disclosure are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. § 1.824 for the following reason(s) set forth. This application contains a sequence listing submitted on computer readable form (CRF) on July 14, 2006 as flawed technically and not entered into database. Full compliance with the sequence rules is required in response to this office action.

Information Disclosure Statement

3. The information disclosure statement filed June 8, 2009 has been considered. An initialed copy is enclosed.

Rejections Withdrawn

4. In view of the Applicants amendment and remarks the following rejections are withdrawn.

a) The rejection of claims 1-2 and 7-8 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-6, and 12 of copending US Application No. 10,536,935 is withdrawn from consideration due to the copending application granted US Patent No. 7,541,332 Date June 2, 2009.

b) Rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Tsukahara et al WO/2002/004626 Date January 17, 2002 is withdrawn in light applicants arguments thereto.

c) Rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Tsukahara et al WO/2002/004626 Date January 17, 2002 in view of Cardoso De Almeida WO/1995/022614 Date August 24, 1995 is withdrawn in light applicants arguments.

d) Rejection of claims 1-8 under 35 U.S.C. 103(a) as being unpatentable over Weinstock et al US Patent No. 6,747,137 Date June 8, 2004 US Filing Date February 12, 1999 in view of

Tsukahara et al WO/2002/004626 Date January 17, 2002, and Cardoso De Almeida et al WO/1995/022614 Date August 24, 1995 is withdrawn in light applicants arguments.

New Objections

Specification

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

a) The disclosure is objected to because of the following informalities: the phrases "GlcN-(acyl)PI", "GPI", and "GPI-anchored" (see pgs. 1-2) should be out for the first time of use. Appropriate correction is advised.

b) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see pg. 3 lines 25-30). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

c) The use of the trademarks Complete™ (see pg. 9 lines 10-20) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

6. Claim 1-6 and 9-10 are objected to because of the following informalities: As to independent claim 1 and dependent claims 2-6 and 9-10, the claims contains the abbreviations "GlcN-(acyl)PI", "GPI", and "GPI-anchored". While acronyms are permissible shorthand in the claims, the first recitation should include the full recitation followed by the acronym in parenthesis for ex. glucosaminyl-acylphosphatidylinositol (GlcN-(acyl)PI). Appropriate correction is required.

New Grounds of Rejections

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ormum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-2 and 9-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 7,541,332.

In the instant case, the instant claims are drawn to a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI (claim 1), wherein the GWT1 gene is any one of the following: (a) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14; (b) a DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13; (c) a DNA hybridizing to the DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13 under stringent conditions; and (d) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14, wherein one or more amino acids have been added, deleted, substituted, and/or inserted (claim 2), wherein the step of detecting acylated GPI is thin-layer chromatography (claim 3), wherein the method further comprises a step 4, determining whether the selected test sample inhibits the process of transporting a GPI- anchored protein to a fungal cell wall, whether the test sample inhibits the expression of a GPI- anchored protein on a fungal cell surface, or whether the test sample inhibits the proliferation of a fungi (claims 5 and 9-10).

Claims 1-3 of U.S. Patent No. 7,541,332 teach a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein (SEQ ID NO: 4) encoded by the GWT1 gene (SEQ ID NO:3); (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI (see claims 1-2), wherein the method further comprises a step 4, of determining whether the selected test sample inhibits the process of transporting a GPI- anchored protein to a fungal cell wall, whether the test sample inhibits the expression of a GPI- anchored protein on a fungal cell surface, or whether the test sample inhibits the proliferation of a fungi (see claims 2-3)

Although the conflicting claims are not identical, they are not patentably distinct. The U.S. Patent No. 7,541,332 recites the "the method". The species of the method anticipate the genus claims of any method.

Thus, claims 1-2 and 9-10 encompassing the "the method" in the present application are obvious over claims 1-3 of U.S. Patent No. 7,541,332 June 2, 2009.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description

8. Claims 1-6 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

The claims are drawn to a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI (claim 1), wherein the GWT1 gene is any one of the following: (a) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14; (b) a DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13; (c) a DNA hybridizing to the DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13 under stringent conditions; and (d) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14, wherein one or more amino acids have been added, deleted, substituted, and/or inserted (claim 2), wherein the step of detecting acylated GPI is thin-layer chromatography (claim 3), wherein the method further comprises a step 4, determining whether the selected test sample inhibits the process of transporting a GPI- anchored protein to a fungal cell wall, whether the test sample inhibits the expression of a GPI- anchored protein on a fungal cell surface, or whether the test sample inhibits the proliferation of a fungi (claims 5 and 9-10).

The specification discloses proteins and protein mutants can be prepared by hybridization techniques normally have high homology to proteins consisting of the amino acid sequence (see pg. 3 lines 15-25). The specification discloses the detection of acylated GPI in GWT1 gene-introduced wild-type strain isolated from *Saccharomyces Cerevisiase (S. Cerevisiase)*, which suggesting the decrease of GlcN-(acyl)PI when a compound having activity of inhibiting the activity of GWT1 gene is present in an assay (see pg. 10 lines 1-15). The specification further discloses GlcN-(acyl)PI can be used as an indicator when screening for compounds that inhibit acylation by adding compounds to acylated GPI in an assay to measure the activity of inhibiting GPI acylation. The specification discloses the compounds screened in Examples (B2, B60, B73, and B85), which discloses the GWT1 gene. The specification is only limited the *S. Cerevisiae* GWT1 gene comprising the nucleotide sequence of SEQ ID NO:1 capable of decreasing GlcN-(acyl)PI. Applicant has not shown how the *S. Cerevisiae* GWT1 gene comprising the nucleotide sequence of SEQ ID NO:1, detecting GlcN-(acyl)PI with SEQ ID NO: 1, and decreasing GlcN-(acyl)PI indicates a compound has been screened for antifungal activity. Applicant has not shown how any GWT1 gene contacts a test sample, how any GWT1 gene detects GlcN-(acyl)PI,

and then selecting a test sample that decreases GlcN-(acyl)PI indicates a compound has been screened for antifungal activity. As a result Applicant has not shown the correlation of SEQ ID NO: 1 (or any fragment, complement etc.) with the steps 1), 2), and 3), with the function as directed aforementioned above, and furthermore, Applicant has not shown the correlation of the genus of GWT1 gene, with the function as directed aforementioned above. Therefore, the performance of said method steps 1) 2) and 3) do not correlate to the outcome as claimed.

Furthermore the limited number of species aforementioned above and disclosed in the specification is not deemed to be representative of the genus of GWT1 gene encompassed by the instant claims. Moreover, Applicant is reminded that adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. Therefore, although the specification discloses examples GWT1 gene, the specification does not teach any structural limitations and the specification is silent to the correlation of its recited function.

The specification does not describe any DNA variants generated from mutations: substitution, deletion, insertion, addition (e.g., fusion), any protein mutants encoded by the DNA variant thereof capable of decreasing of glycosaminyl-acylphosphatidylinositol (GlcN-(acyl)PI) and the capability of inhibiting fungal glycosylphosphatidylinositol (GPI) anchored protein in the cell wall of fungus. The specification does not describe any sequences and/or fragments which hybridize to any nucleotide as claimed capable of decreasing of GlcN-(acyl)PI and capable of inhibiting fungal GPI anchored protein in the cell wall of fungus.

The specification doesn't explicitly define what constitutes stringent conditions. Therefore a DNA hybridizing to the DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13 under stringent conditions leads to unpredictable results. Moreover, hybridization under stringent conditions would be expected to permit a great deal of variation between the two hybridizing sequences, making it even more unpredictable that the two sequences would share the same function.

Moreover, the scope of the claims includes numerous structural variants/analogues, and the genus is highly variant because a significant number of structural differences between genus members are permitted. Therefore the disclosure fails to describe the common attributes or

characteristics that identify members of the genus, and because the genus is highly variant to screen for a compound having antifungal activity in the method as claimed. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. As to the aforementioned method, the claims are drawn to a large number functional analogue of variants and a polypeptide coded by variants having different possibilities of changes to the amino acid sequences as claimed. The specification does not teach an example of any functional analogue of variants and a polypeptide coded by variants that comprise the method of screening for a compound having any antifungal activity.

Without structural limitations in the claimed method comprising , (a) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14; (b) a DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13; (c) a DNA hybridizing to the DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13 under stringent conditions; and (d) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14, wherein one or more amino acids have been added, deleted, substituted, and/or inserted of the screening of a compound having antifungal activity in any method; the written description is not deemed to be fulfilled and the specification lacks proper written description of the claimed method as set forth *supra*. This issue is best resolved by Applicants pointing to the specification by page and line number where description of the claimed invention is set forth.

Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of (a) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14; (b) a DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13; (c) a DNA hybridizing to the DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13 under stringent conditions; and (d) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14, wherein one or more amino acids have been added, deleted, substituted, and/or inserted, the screening of a compound having antifungal activity for the claimed method, the skilled artisan could not immediately recognize or distinguish members of the claimed genus of GWT1 gene. Therefore, in accordance with the Guidelines, the description

is not deemed representative and thus does not meet the written description requirement.

Enablement

9. Claims 1-6 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting the function of GWT1 gene, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein (SEQ ID NO:2) encoded by the GWT1 gene (SEQ ID NO: 1); (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI, does not reasonably provide enablement for a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; wherein the GWT1 gene is any one of the following: (a) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14; (b) a DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13; (c) a DNA hybridizing to the DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13 under stringent conditions; and (d) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14, wherein one or more amino acids have been added, deleted, substituted, and/or inserted (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)).
There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;
(B)The nature of the invention;
(C)The state of the prior art;
(D)The level of one of ordinary skill;

(E)The level of predictability in the art;

(F)The amount of direction provided by the inventor;

(G)The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Nature of the invention

The claims are drawn to a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI (claim 1), wherein the GWT1 gene is any one of the following: (a) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14; (b) a DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13; (c) a DNA hybridizing to the DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13 under stringent conditions; and (d) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14, wherein one or more amino acids have been added, deleted, substituted, and/or inserted (claim 2), wherein the step of detecting acylated GPI is thin-layer chromatography (claim 3), wherein the method further comprises a step 4, determining whether the selected test sample inhibits the process of transporting a GPI- anchored protein to a fungal cell wall, whether the test sample inhibits the expression of a GPI- anchored protein on a fungal cell surface, or whether the test sample inhibits the proliferation of a fungi (claims 5 and 9-10).

The breadth of the claims

The product being used to screen for a compound having antifungal activity comprises:

(a) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14;

(b) a DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13;

(c) a DNA hybridizing to the DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13 under stringent conditions; and

(d) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14, wherein one or more amino acids have been added, deleted, substituted, and/or inserted is overly broad. Therefore it is hard for one skilled in the art to determine if steps 1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene, 2) detecting GlcN-(acyl)PI; and 3) selecting the test sample that decreases GlcN-(acyl)PI can be used for screening for a compound having antifungal activity. Furthermore it is hard for one skilled in the art to determine if the performance of said method steps 1) 2) and 3) correlate to the outcome of screening for a compound having antifungal activity.

The Quantity of Experimentation Required

The quantity of experimentation required to practice the invention as claimed would be undue as it would require novel and unknown species that will correlate to steps 1) 2) and 3) as set forth *supra* to screen for a compound having antifungal activity. Since the specification fails to provide particular guidance for screen for a compound having antifungal activity as set forth supra it would require undue experimentation to practice the invention over the broad scope as presently claimed.

Guidance in the specification/Working Examples

The specification discloses proteins and protein mutants can be prepared by hybridization techniques normally have high homology to proteins consisting of the amino acid sequence (see pg. 3 lines 15-25). The specification discloses the detection of acylated GPI in GWT1 gene-introduced wild-type strain isolated from *Saccharomyces Cerevisiase (S. Cerevisiase)*, which suggesting the decrease of GlcN-(acyl)PI when a compound having activity of inhibiting the activity of GWT1 gene is present in an assay (see pg. 10 lines 1-15). The specification further discloses GlcN-(acyl)PI can be used as an indicator when screening for compounds that inhibit acylation by adding compounds to acylated GPI in an assay to measure the activity of inhibiting GPI acylation. The specification discloses the compounds screened in Examples (B2, B60, B73, and B85), which discloses the GWT1 gene. The specification is only limited to the *S. Cerevisiae* GWT1 gene comprising the nucleotide sequence of SEQ ID NO:1 capable of decreasing GlcN-(acyl)PI. Applicant has not shown how the *S. Cerevisiae* GWT1 gene comprising the nucleotide

sequence of SEQ ID NO:1, detecting GlcN-(acyl)PI with SEQ ID NO: 1, and decreasing GlcN-(acyl)PI indicates a compound has been screened for antifungal activity. Applicant has not shown how any GWT1 gene contacts a test sample, how any GWT1 gene detects GlcN-(acyl)PI, and then selecting a test sample that decreases GlcN-(acyl)PI indicates a compound has been screened for antifungal activity. As a result Applicant has not shown the correlation of SEQ ID NO: 1 (or any fragment, complement etc.) with the steps 1), 2), and 3), with the function as directed aforementioned above, nor has Applicant shown the correlation of the genus of GWT1 gene, with the function as directed aforementioned above.

The specification doesn't define hybridization under stringent conditions. Therefore a DNA hybridizing to the DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13 under stringent conditions which leads to unpredictable results. Moreover, hybridization under stringent conditions would be expected to permit a great deal of variation between the two hybridizing sequences, making it even more unpredictable that the two sequences would share the same function. Moreover, the scope of the claims includes numerous structural variants/analogues, and the genus is highly variant because a significant number of structural differences between genus members are permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant to screen for a compound having antifungal to describe the genus. As to the aforementioned method, the claims are drawn to a large number functional analogue of variants and a polypeptide coded by variants having different possibilities of changes to the amino acid sequences as claimed.

Applicant has not shown how any GWT1 gene contacts a test sample, how any GWT1 gene detects GlcN-(acyl)PI, and then selecting a test sample that decreases GlcN-(acyl)PI indicates a compound has been screen for antifungal activity. Moreover, Applicant has not shown the correlation of the genus of GWT1 gene, with the function as directed with the method aforementioned above. The specification does not teach an example of any functional analogue of variants and a polypeptide coded by variants that comprise the method of screening for a compound having antifungal activity. Therefore, Applicant has not shown how the performance of said method steps 1) 2) and 3) correlate to the outcome(screening for antifungal activity) as claimed. Since the disclosure fails to provide any working example of steps 1), 2), and 3)

correlating with the function as claimed nor has the disclosure shown variant polynucleotides and/or the subsequences that hybridize the genus to correlate with function as claimed, the specification as filed fails to provide guidance with the method of screening a compound as set forth supra.

In conclusion, the claimed inventions are not enabled for a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; wherein the GWT1 gene is any one of the following: (a) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14; (b) a DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13; (c) a DNA hybridizing to the DNA comprising the nucleotide sequence of SEQ ID NO: 1, 3, 5, 7, 9, 11, 12, or 13 under stringent conditions; and (d) a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO: 2, 4, 6, 8, 10, or 14, wherein one or more amino acids have been added, deleted, substituted, and/or inserted (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI. The product comprising (a), (b), (c), and (d) being used for screening the compound as set forth supra is overly broad. The specification doesn't define hybridization under stringent conditions. Moreover, hybridization under stringent conditions would be expected to permit a great deal of variation between the two hybridizing sequences, making it even more unpredictable that the two sequences would share the same function. Applicant has not shown how any GWT1 gene contacts a test sample, how any GWT1 gene detects GlcN-(acyl)PI, and then selecting a test sample that decreases GlcN-(acyl)PI indicates a compound has been screened for antifungal activity. Therefore, Applicant has not shown how the performance of said method steps 1) 2) and 3) correlate to the outcome(screening for antifungal activity) as claimed. The specification does not teach an example of any functional analogue of variants and a polypeptide coded by variants that comprise the method of screening for a compound having antifungal activity. As a result, for the reasons discussed above, it would require undue experimentation for one skilled in the art to use the claimed methods.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-6 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to independent claim 1, reciting the phrase "detecting GlcN-(acyl)PI", this phrase is vague and indefinite in whether or not the detection is performed for binding of the protein to a sample which contain or does not contain the compound (note that the instant claim as written does not clearly set forth said sample must contain the compound) or/and for binding of the protein to the compound in said sample only. Clarification in this regard is required.

11. Claims 1-6 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

As to claim 1 independent claim and all dependent claims 2-6 and 9-10. Claim 1 is drawn to a method of screening for a compound having an antifungal activity, wherein the method comprises the steps of: (1) contacting a test sample with an overexpressed protein encoded by the GWT1 gene; (2) detecting GlcN-(acyl)PI; and (3) selecting the test sample that decreases GlcN-(acyl)PI. However the performance of said method steps 1) 2) and 3) do not correlate to the outcome as claimed. Therefore, said method steps do not lead to stated method goal.

Conclusion

12. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nina A. Archie whose telephone number is 571-272-9938. The examiner can normally be reached on Monday-Friday 8:30-5:00p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Nina Archie
Examiner
Art Unit 1645

/Robert A. Zeman/
for Nina Archie, Examiner of Art Unit 1645